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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,231	11/17/2000	Susan R. Webb	TSRI 536.1Div1	7187

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THE SCRIPPS RESEARCH INSTITUTE  
10550 North Torrey Pines Road  
Mail Drop: TPC-8  
La Jolla, CA 92037

EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/715,231

Applicant(s)

WEBB ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-60 is/are pending in the application.
- 4a) Of the above claim(s) 34,37,38,48,49,53-55 and 58-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,35,36,39-47,50-52,56 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's amendment filed 1-21-03 is acknowledged and has been entered.

#### ***Drawings***

The corrected or substitute drawings were received on 1-21-03. These drawings are acceptable.

#### ***Oath/Declaration***

In view of the replacement declarations filed 1-21-03, the objection to the oath has been withdrawn.

#### ***Specification***

In view of the Abstract filed 1-21-03, the objection to the specification has been withdrawn.

#### ***Priority***

In view of Applicant comments, priority is given to the provisional application 60/018175.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MAINTAINED Claims 33, 35-36, 39-43, 45-47, 50-52 and 56-57 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### **Response to Arguments**

Applicant traverses the rejection on the grounds that in the Enzo case, the requirement for written description may be satisfied in the knowledge of the art the disclosed function is sufficiently correlated to a particular known structure, and that in Amgen which referred to mammalian and vertebrate cell types that could be used to express recombinant human EPO, the courts found that the words mammalian and vertebrate conveyed distinguishing information that was readily understood by one of ordinary skill in the art. The examiner notes that it is well known in the art that mammalian and vertebrate cell types are suitable hosts for recombinant genes. Applicant contends that the terms of a cell, a MHC Class II heterodimer and an accessory molecule are well known to one of ordinary skill in the art at the time the invention was made.

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However it is noted that the instant claims are drawn to a synthetic antigen presenting cell comprising a support and an extracellular portion of a recombinant MHC Class II heterodimer and at least one recombinant accessory molecule, is not as routine as a mammalian cell that expresses a foreign gene, such as that encoding EPO. Applicant contends that the specification discloses exemplary cells, MHC Class II genes and heterodimers, as well as accessory genes and encoded proteins. However, given the absence of a definition in the instant specification of the term accessory molecule, and given the divergent structures and functions of the accessory molecules disclosed (costimulatory molecules, adhesion molecules and survival molecules), the genus of said accessory molecules that would be effective in the recited synthetic antigen presenting cell, would not be readily apparent to one of skill in the art, without further guidance from the specification. Thus with the exception of a method comprising the accessory molecules of B7.1, B7.2, ICAM-1, ICAM-2, ICAM-3, FASL, CD70 and LFA, there is inadequate written description for the recited synthetic antigen comprising the breadth of the accessory molecules encompassed by the instant claims, without further description from the specification.

### ***Double Patenting***

MAINTAINED Claims 33, 35-36, 41-43, 44-47, 50-52 and 56-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,355,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims in the '479 patent is more narrow than the scope of the claims in the instant application.

### ***Response to Arguments***

Applicant states that upon a notice of Allowable subject matter, a terminal disclaimer will be submitted.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

WITHDRAWN Claims 33, 35-36, 41-42, 44-47, 50-52 and 56-57 are rejected under 35 U.S.C. 102(e) as being anticipated by MacKay et al. US Patent 5,648,219.

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### *Response to Arguments*

In view of applicant's amendment filed 1-21-03, which added the limitation of said synthetic antigen presenting cell encompassing recombinant molecules, the art rejection has been withdrawn.

### *New Grounds of Rejection*

Claims 33, 35-36, 41-42, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Galvin et al (Journal of Immunology 149:3802-3808, 1992)(IDS).

Galvin et al teach a synthetic antigen presenting cell comprised of a support (CHO cells) and recombinant MHC Class II molecules and the recombinant accessory molecule B7, (see entire article, including the Abstract and page 3803, column 1). Therefore the referenced teachings anticipate the claimed invention.

Claims 33, 35-36, 41-42, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Baskar et al (Journal of Immunotherapy 14:209-215, 1993)(IDS).

Galvin et al teach a synthetic antigen presenting cell comprised of a support (CHO cells) and recombinant MHC Class II molecules and the recombinant accessory molecule B7, (see entire article, including the Abstract and page 210, column 1). Therefore the referenced teachings anticipate the claimed invention.

### *Conclusion*

No Claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 1-21-03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
April 3, 2003

  
Patrick J. Nolan, Ph.D.,  
Primary Patent Examiner,  
Group 1640